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Idaho Board of Pharmacy

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Clifford E. Barnett, RPh, and Merl Dalton, RPh

Cliff Barnett, former executive director of the Idaho Board of Pharmacy, and Merl Dalton, a 14-year member of the Idaho Board of Pharmacy, recently passed away.

Cliff was born in Cottonwood, ID, in 1917. After graduating from Grangeville High School in 1941, Cliff enlisted in the service. He married Rose Johnston of Grangeville in July 1942. Cliff served a distinguished and highly decorated career in the Army Air Corps until the end of World War II. Following the war, Cliff attended Idaho State University earning his degree in pharmacy. After graduation Cliff bought a pharmacy in Nezperce, ID, where he and Rose lived for 12 years until Cliff took a position in Boise as the executive director of the Board. He held this position from 1965 until his retirement in 1980.

Merl D. Dalton was born and raised in Pocatello and attended Idaho State University, graduating in 1949 with a degree in pharmacy. Merl served with the Marine Corps during World War II. He saw action in the Pacific and, among other commendations, was awarded two Purple Heart medals. Merl owned and operated Marketime Drug in Lewiston, ID, for many years until his retirement. He served as president of the Idaho Pharmaceutical Association from 1959 to 1960. He served in the House of Delegates and seldom missed a meeting. Merl received a special recognition award from the Board of Pharmacy for 50 years of commitment spanning from 1951 to 2001. Merl and his wife Diana had many friends in pharmacy and continued to participate in Association functions well after his retirement.

Board of Pharmacy Analysis and Protocol of Electronic Prescriptions for Idaho

Analysis

The Board office has been receiving numerous inquiries regarding electronic prescriptions as well as requests for approval of various electronic prescription programs. The following sets out a protocol of basic requirements for electronic prescriptions based on the Pharmacy Act, Board Rules, and the Uniform Electronic Transactions Act (UETA) – Title 28 Chapter 50 Idaho Code.

The UETA requires recognition of electronic signatures unless separate applicable law contains requirements such as a specific means of sending, communicating, or transmitting the signed record, which are inconsistent with electronic transmission and signature.

With the exception of controlled substance prescriptions, the law applicable to prescriptions does not require any particular means of sending, communicating, or transmitting the prescription that is inconsistent with electronic transmission or signature.

A prescription must be issued by a practitioner acting in the usual course of his or her profession.

A prescription must contain certain minimum written information and be signed by the prescriber.

The UETA defines "signature" as an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

The UETA applies only to transactions between parties, each of which has agreed to conduct transactions by electronic means; however, this "agreement" is determined from the context and surrounding circumstances including the parties' conduct.

Protocol

Applying the above, the following provides a protocol for evaluating whether or not a proposed program will produce a valid electronic prescription.

1. Controlled substance prescriptions cannot bear electronic signatures or be transmitted via electronic means.
2. All information that is required to appear on a traditional paper prescription must appear in the electronic prescription. This includes the electronic signature of the prescriber.
3. Just as each traditional paper prescription must be signed, so must each electronic prescription. This means that for each electronic prescription, the prescriber must individually perform the electronic function described in IC 28-50-102(8) necessary to attach or logically associate the practitioner's electronic signature to the electronic prescription.
4. In the same fashion that a practitioner is prohibited from pre-signing prescriptions, a practitioner is prohibited from using electronic means to automatically sign prescriptions.

Specific requirements that the pharmacy maintain paper files at the pharmacy for inspection by Board of Pharmacy inspectors remain in place.

New Over-the-Counter Product Labeling

On March 24, 2004, Food and Drug Administration (FDA) passed final rulings requiring content labeling for over-the counter (OTC) medications that contain levels of calcium, magnesium, sodium, or potassium that might be harmful to persons with certain underlying medical conditions. The final rule was effective April 23, 2004, with compliance expected by September 24, 2005. The labeling changes for oral OTC products were deemed necessary as persons with certain medical conditions such as heart disease, hypertension, kidney disease, kidney stones, or other medical conditions could worsen their condition upon consumption of these products. For example, OTC use of medications containing potassium may cause hyperkalemia in persons with compromised renal function. Under the new rules, oral OTC medications must state the exact amount of a particular ingredient in each dose if they contain:

- 5 mg or more of sodium in a single dose,
- 20 mg or more of calcium in a single dose,
- 8 mg or more of magnesium in a single dose, or
- 5 mg or more of potassium in a single dose.

The rules also require warnings to alert consumers on sodium-, calcium-, magnesium-, or potassium-restricted diets to consult their physician before using oral products that contain maximum daily doses of:

- more than 140 mg sodium,
- more than 3.2 grams calcium,
- more than 600 mg magnesium, or
- more than 975 mg potassium.

Currently the new label requirements do not include mouth rinses, fluoride toothpastes, or mouth washes. Detailed information on the rulings can be found in the Federal Register at www.fda.gov/OHRMS/DOCKETS/98fr/04-6479.htm and www.fda.gov/OHRMS/DOCKETS/98fr/04-6480.htm.

FDA Requests Antidepressant Manufacturers to Strengthen Warnings

On March 22, 2004, FDA issued a public health advisory that cautions physicians, their patients, and families and caregivers to closely monitor adults and children with depression. Results of antidepressant studies in children since June 2003 appeared to suggest an increased risk of suicidal thoughts and actions in those children taking certain antidepressants. FDA has initiated a review of these reports, but it is not clear whether or not antidepressants contribute to suicidal thinking and behavior.

As a result of the studies, FDA is asking manufacturers to change the labels of 10 drugs to include stronger cautions and warnings to monitor patients for worsening depression and the emergence of suicidal ideation. The drugs affected include bupropion (Wellbutrin®), citalopram (Celexa™), escitalopram (Lexapro™), fluvoxamine (Luvox® – not FDA approved for treatment of depression in the US), fluoxetine (Prozac®), mirtazapine (Remeron®), nefazodone (Serzone®), paroxetine (Paxil®), venlaxafine (Effexor®), and sertraline (Zoloft®). It should be noted that Prozac is the only drug approved for use in children with major depressive disorder. Prozac, Zoloft, and Luvox are approved for pediatric patients with obsessive-compulsive disorder.

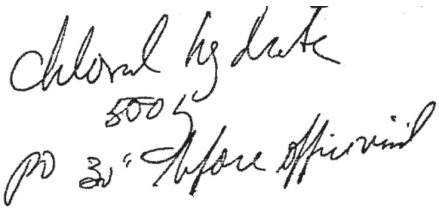
Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy with antidepressants is believed to have the potential to induce manic episodes in such patients. A causal relationship has not been established between physical symptoms and suicidal ideation; however, medications may need to be discontinued when the symptoms are severe, abrupt in onset, or were not part of the presenting symptoms. Further information can be found on CDER's Web site: www.fda.gov/cder/drug/antidepressants/default.htm.

Let Past Experience with Chloral Hydrate Syrup Guide its Safe Use

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Chloral hydrate can be used safely to sedate pediatric patients for diagnostic procedures such as endoscopic procedures, CT scans, or MRIs. However, in several error reports over the years we have seen the sad stories of fatalities that have occurred after excessive doses of the drug were dispensed in error. Typically, deaths have occurred in cases where the order was not clear or when untrained individuals, both staff and parents, were involved without adequate supervision or the knowledge that they were administering an overdose. In some cases, to save time, chloral hydrate has been prescribed for use at home prior to travel to the practice site. In one instance, a 500 mg/5 mL concentration was dispensed instead of 250 mg/5 mL, which also is available. Unfortunately, the dose was prescribed by volume (teaspoonful), which made detection of the twofold overdose impossible. In another incidence, 120 mL of syrup was incorrectly dispensed instead of the prescribed 12 mL. The label instructed the mother to give her child the entire bottle, which she did. Without trained personnel and emergency equipment present to treat these accidental overdoses, the children in both cases died.

Recently the tragedy happened again. A prescription was written for a 17-month-old child; the pharmacist read the directions as "30 cc before office visit" and instructed the mother to give her child that amount. In truth, the physician wanted the child to receive 500 mg 30 *minutes* before the office visit. The double hash-mark symbol ("), which the physician intended to mean minutes, was misread as cc. Actually, a double hash mark stands for seconds; a single hash mark (') is used for minutes. Neither symbol should be used in medicine, however, because not everyone understands their meaning.



Errors also happen in diagnostic areas where technical support personnel often administer oral conscious sedation even though they are not properly trained. In some cases, an ambiguous physician order such as "give chloral hydrate 5 cc prn sedation" or ". . . prn agitation," rather than a specific milligram amount and maximum dose, has led to events where multiple doses of chloral hydrate were dispensed from the supply available to personnel. By the time the child fell asleep, the amount administered was a massive overdose leading to respiratory arrest.

Please consider reviewing your process for dispensing oral liquids used for conscious sedation in children, whether to a medical facility or to a family member. We suggest that the following precautions, in addition to package insert recommendations, be employed. Advise physicians that the drug should not be prescribed by volume (eg, "5 mL," "one teaspoonful," etc). There are two available concentrations of this drug. Instead, the specific milligram dose should be expressed. The prescription should state that it is for pre-procedure sedation. In hospital situations or when pharmacies dispense to health care facilities, prescriptions are best dispensed for each patient in labeled, unit-dose, oral syringes; providing the product in bulk packages as floor stock is less safe. We believe it is safest for pharmacists to *not* dispense prescriptions for patient use in the home when it is for pre-procedure sedation. Should the caregiver receive such a prescription, he or she should be advised that they are safest for the dose to be administered where the procedure will be performed. Official labeling for Versed® Syrup, another drug used for conscious sedation in children, notes that the syrup is intended for use only in monitored settings, never the home. Also, as noted in the product's boxed warning, only health care professionals trained in conscious sedation procedures and authorized to administer conscious sedation drugs should do so. Careful monitoring by direct visual observation is necessary and age-/size- appropriate resuscitation equipment must be readily available. The American Academy of Pediatrics agrees; the Academy's current "Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures" (*Pediatrics* 2002; 110:836-838) recommend that children should not receive sedative or anxiolytic medications without supervision by skilled medical personnel. These medications should be administered by, or in the presence of, individuals skilled in airway management and cardiopulmonary resuscitation and administered in a health care facility where appropriate monitoring, including continuous pulse oximetry, can be instituted.

One final argument for administering children's sedation on site is to ensure proper timing in case of unpredictable schedule delays.

NABP Releases Updated NAPLEX Blueprint

NABP has released the updated blueprint for the North American Pharmacist Licensure Examination™ (NAPLEX®). The blueprint is available for viewing on NABP's Web site, www.nabp.net, as of September 2004. Examinations based on the updated blueprint will be administered beginning spring 2005.

Changes to the NAPLEX blueprint include the addition of competency statements addressing dietary supplements and pharmacotherapeutic equivalency as well as integration of the skill of communicating with patients and other health care providers in the entire examination blueprint instead of focusing it within a single competency area as with the current NAPLEX. The examination continues to consist of three major areas that are divided into several competency and subcompetency statements.

The updated blueprint and competency statements require a new passing standard. However, the NAPLEX continues to be a computer-adaptive examination that requires a scaled score of 75 or greater to pass. Calculation of the score is the same as in the past: the score is calculated by first determining the candidate's ability level on the NAPLEX and then comparing this to the predetermined minimum acceptable ability level established for the NAPLEX. The new passing standard will go into effect along with the updated blueprint in spring 2005.

For more information about the NAPLEX, contact the Customer Service Department by calling 847/391-4406 or visit the Association's Web site at www.nabp.net.

December 2004 FPGEE Date and Location Announced

On December 4, 2004, NABP will again administer a paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). The examination is being offered at three United States locations: Northlake (Chicago area), IL; New York, NY; and San Mateo, CA. Candidates who have been accepted to sit for the December 4, 2004 administration were mailed their admission tickets in early fall.

To prepare for the December examination, candidates may take the Pre-FPGEE™, a Web-based practice examination for the FPGEE. The practice examination is accessible at www.nabp.net and www.pre-fpgee.com.

For more information on the FPGEE, visit NABP's Web site at www.nabp.net.

Controlled Substance Registrations

By the time you receive this *Newsletter*, you should have received your renewal notice for your Controlled Substance Registration. If for some reason you did not receive a renewal, you can obtain one by accessing the Board's Web site at www.state.id.us/bop. Remember, your renewals must be postmarked by December 31, 2004, or a late charge of $75 will be added to the cost of the registration. Keep in mind also that you would not be able to work in a pharmacy without a Controlled Substance Registration.

PIC Responsibilities

The Board continues to discover violations regarding the designation of pharmacists-in-charge (PIC) within pharmacies throughout Idaho. There should not be a single day that a pharmacy is in operation without an individual being designated as PIC of that facility. In the event that a PIC suddenly departs and the pharmacy is unable to quickly obtain a replacement to serve as permanent PIC, he or she can designate any licensed pharmacist willing to accept the role as an interim PIC for a short period of time (not to exceed 30 days).

The interim PIC must still complete a Pharmacist-In-Charge (PIC) Responsibility Checklist and will be held responsible for all pharmacy-related matters until such time as a permanent PIC is designated. Do not take the job if you are not willing to accept the responsibilities that go along with the position of PIC. The Board of Pharmacy holds the PIC of each pharmacy responsible for all pharmacy-related matters. The following is a noninclusive list of Board Rules that relate to the responsibilities of pharmacists moving into the role of PIC.

- Rule 156. PHARMACIES. All sections
- Rule 496. CONTROLLED SUBSTANCE INVENTORY. All sections
- Rule 251. PHARMACY TECHNICIANS. All sections

Please ensure that your pharmacy has the current edition of the Idaho Pharmacy Laws & Rules prior to reviewing the designated rule sections.

Registrations for Technicians

The Board inspectors are still finding new technicians or technicians that have changed locations and are working without having received their technician registration. Rule 251.7.b. Initial Registration states that before commencing duties as a pharmacy technician (including previously registered pharmacy technicians who are changing pharmacies), an individual must register with the Board, pay the fee, and have received a certificate of registration. If you are a registered pharmacy technician and you are changing your work location you must fill out a Work Location Change form prior to commencing work at the new pharmacy site. There is no additional fee required when submitting a work location change.

Pharmacy technicians and the PIC of the pharmacy are both equally responsible for making sure the pharmacy technician is properly registered at all times.

Update on In-House Reporting of Controlled Substances

As of September 1, 2004, the Idaho Board of Pharmacy began collecting controlled substance prescriptions "in-house." So far, the transmission of data directly to the Board has been working very well. The Board has the ability to collect data via disk, CD, e-mail, or FTP. The only form of transmission not available is via modem. A reminder to all reporting community and mail-service pharmacies: data is still required to be submitted by the first of every month for the previous month's prescriptions.

There is no change in the data requirements or the date for submitting data. If you are experiencing any problems with submission of your data they should be immediately reported to Teresa at the Board of Pharmacy at 208/334-2356.

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